FDA Finalizes Informed Consent Guidance for Clinical Investigations



10/31/2023

On September 18, 2023, the U.S. Attorney's Office, District of New Jersey, announced two pharmacy executives and a pharmacist were arraigned on charges of defrauding Medicare and TriCare of \$33 million dollars. Each of the three defendants was charged with conspiracy to commit health care fraud and wire fraud. Additionally, the CEO/owner of Apogee Bio-Pharm LLC in Edison, New Jersey (the Pharmacy) and the director of operations of the Pharmacy were charged with wire fraud, conspiracy to violate the federal anti-kickback statute, and payment of illegal kickbacks.

Pursuant to the indictment, the defendants allegedly worked with marketing companies that pressured Medicare and TriCare beneficiaries to try expensive medications that were medically unnecessary. The marketing companies then sent pre-marked prescription pads for particular drugs that would produce high reimbursement to telemedicine companies. The telemedicine companies then paid doctors to approve prescriptions. The marketing companies paid the telemedicine companies kickbacks for every beneficiary referred for a prescription. The marketing companies then directed the prescriptions to the Pharmacy and the Pharmacy filled the prescriptions and sought reimbursement from federal health care benefit programs. The Pharmacy paid a portion of the reimbursement to the marketing companies as a kickback.

The defendants face the following penalties if convicted: (i) the health care fraud and wire fraud conspiracy charges carry a maximum potential penalty of 20 years in prison; (ii) the health care fraud charges carry a maximum potential penalty of 10 years in prison; (iii) the wire fraud charges carry a maximum potential penalty of 20 years in prison; (iv) the charge of conspiracy to violate the Anti-Kickback Statute carries a maximum potential penalty of five years in prison; (v) and the charges of payment of illegal kickbacks are punishable by 10 years in prison. Each count is punishable by a fine of \$250,000, or twice the gain or loss from the offense, whichever is greatest.

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For more information, contact:

Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com Edward J. Yun | 973.364.5229 | eyun@bracheichler.com Cynthia J. Liba | 973.403.3106 | cliba@bracheichler.com

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